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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,882

03/19/2004

Stephen James Field

0119/0034

7153

21395

7590

09/15/2008

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EXAMINER

ROY, BAISAKHI

ART UNIT

PAPER NUMBER

3737

MAIL DATE

DELIVERY MODE

09/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,882	Applicant(s) FIELD ET AL.	
	Examiner BAISAKHI ROY	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 3-18 have been considered but are moot in view of the new ground(s) of rejection with respect to the limitation of the substrate itself being echogenic.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 3 - 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rammler and Sarkis alone in view of Mills (6723052). Rammler as earlier noted is directed to angioplasty catheter construction by interalia extrusion during which microbubbles are added per col. 3 lines 49 - 52. While the vane portion is thin per 5 - 100 mils this is due to the angioplasty application in small vasculature, and Rammler defines an inner and outer device, vane and track either of which may contain the microbubbles, the vane being thicker than the inner tubular member 44, 46 and the dilatable tube portion 42, and the track being thicker than the vane. Sarkis et al notes Rammler and discusses plastic echogenic catheter constructs where in terms of a pacing lead the inner or outer extruded polymer plastic sleeves 34, 38 or 40 of respective Figures 5 and 5 or either extruded catheter plastic layer 42, 44 of Fig. 6 or the outer tube or inner strut of Fig. 8 may be echogenically formed by mixing of

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echogenic particles within the extruded components. Accordingly it may be considered that Sarkis would teach complete layered catheter extrusion when combined with Rammler or conversely, Rammler as cited in Sarkis would evidence the equivalence of bubble mixing into the polymers being extruded into the various catheter wall components of the latter as they are variously thickness apportioned, since Sarkis is simply noting that particle use as opposed to gas bubbles allows more echogenicity with less alteration of overall catheter properties.

The previous reference teaches the use of a substrate that is coated to create an echogenic surface layer but does not explicitly teach the use of a medical device with a substrate that, itself is echogenic. In the same field of endeavor Mills teaches an echogenic device with a body chamber that is made up of gas bubbles that is sequestered between multiple body chambers separated from each other and made up of any kind of biocompatible material including plastic (col. 6 lines 36-47). Therefore the bubble chamber has one or more membranes or walls surrounding it that is free of gas bubbles. The bubbles extend in a continuous region along the length of the device and sized between 1.0 and 100 micrometers and the bubbles are incorporated into the polymer material of the echogenic device (col. 6 lines 48-64). Mills also address manufacturing the device with the echogenic properties incorporated into the device in order to eliminate the need to obtain "echogenically coated" devices post manufacturing (col. 10 lines 30-36). The echogenic substrate is made up of material that is able to be shaped, molded to form the medical device and is biocompatible (col. 11 lines 51-61).

Therefore it would be obvious to one of ordinary skill in the art to use the echogenic device by Mills, which is manufactured with the echogenic properties incorporated into the device, in place of the use of the “echogenically coated” device of the prior cited references such that surface of the device does not have to undergo post-manufacturing modifications, thereby preventing compromising the orientation and functionality of the device such as the visibility of the device during imaging (Mills, col. 2 lines 21-29 lines 37-42).

Conclusion

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art
Unit 3737

BR
/B. R./
Examiner, Art Unit 3737